

Applicants: John P. Moore et al.
Serial No.: 10/489,040
Filed: March 5, 2004
Page 15

REMARKS

Claims 1-24, 28-31, and 34 are pending in the subject application. By this Amendment, applicants have amended claims 1 and 5, and added new claims 74-79. Support for amended claims 1 and 5 may be found in the specification as follows: Claim 1: at page 41, lines 12-14 and lines 25-34, and page 72, lines 15-18; and Claim 5: page 41, lines 14-16. Support for new claims 74-79 may be found in the specification as follows: Claim 74: page 41, lines 14-16; Claim 75: page 39, lines 9-11; Claim 76: page 39, line 10; Claim 77: page 39, line 21 to page 40 line 11; Claim 78: page 41, lines 12-14 and lines 25-34, page 24, lines 1-21, and Figures 13B, 14B, and 15B; and Claim 79: page 41, lines 12-14 and lines 25-34, page 24, lines 9-14, and Figure 14B. Accordingly, the amendments to claims 1 and 5 and the addition of new claims 74-79 do not raise any issue of new matter. Upon entry of this Amendment, 1-24, 28-31, and 34, as amended, and new claims 74-79 will be pending and under examination.

Sequence Listing:

Applicants submit a paper copy of a Sequence Listing attached hereto as **Exhibit A** in compliance with the requirements of §1.821-1.825. In addition, applicants submit herewith the Sequence Listing on the enclosed computer diskette. Moreover, applicants submit as **Exhibit B** a Statement In Accordance With 37 C.F.R. §1.821(f) certifying that the information in the computer readable form and that in the paper copy are the same, and that the Sequence Listing does not introduce new matter.

Applicants: John P. Moore et al.
Serial No.: 10/489,040
Filed: March 5, 2004
Page 16

Restriction Requirement:

In the April 24, 2006 Office Action, the Examiner required restriction under 35 U.S.C. §121 and §372 of pending claims 1-24, 28-31, and 34 to one of the four allegedly patentably distinct inventions.

- I. Claim 1-23, drawn to a composition comprising a pharmaceutically acceptable particle and a stable HIV-1 pre-fusion envelope glycoprotein trimeric complex operably affixed thereto;
- II. Claims 24, 30 and 31, drawn to a method comprising administering to the subject a prophylactically or therapeutically effective amount of the composition;
- III. Claims 28 and 29, drawn to a vaccine which comprises a therapeutically or prophylactically effective amount of the composition; and
- IV. Claim 34, drawn to a method of producing the composition.

The Examiner also indicated that applicants are further required to elect one of the following species:

(i) diameter of particle (one of claims 10-16); and

(ii) agent affixed to the peptide (one of claims 18 and 19).

The Examiner alleged that the inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The Examiner further

Applicants: John P. Moore et al.
Serial No.: 10/489,040
Filed: March 5, 2004
Page 17

alleged that the technical feature linking Groups I-IV appears to be a composition comprising a pharmaceutically acceptable particle and a stable HIV-1 pre-fusion envelope glycoprotein trimeric complex operably affixed thereto, which is shown by Sanders et al. in view of Creson et al. to lack an inventive step. The Examiner thus concludes that the common technical feature does not make a contribution over the prior art.

The Examiner further states that, upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

The Examiner also stated on page 4 of the April 24, 2006 Office Action that if applicants elect claims to the product, withdrawn process claims that depend from or otherwise require all limitations of the allowable product claims will be considered for rejoinder. The Examiner further stated that in the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and that the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. §1.104.

In response, applicants hereby elect, with traverse, to prosecute the invention identified by the Examiner as Group I, claims 1-23. In addition, applicants hereby elect (i) the diameter of the particle set forth in claim 10 (10nm to 100µm), and (ii) the agent set forth in claim 19 (antibody).

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more

Applicants: John P. Moore et al.
Serial No.: 10/489,040
Filed: March 5, 2004
Page 18

independent and distinct inventions are claimed in one application. Nevertheless, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups II-IV would not impose a serious burden once the prior art relevant to Group I has been identified. Therefore, there would be no serious burden on the Examiner to examine Groups I-IV together in the subject application.

In view of the foregoing, applicants maintain that restriction under 35 U.S.C. §121 and §372 is not proper, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

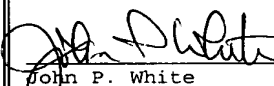
Applicants: John P. Moore et al.
Serial No.: 10/489,040
Filed: March 5, 2004
Page 19

No fee, other than the \$150.00 fee for additional claims, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
 John P. White Registration No. 28,678	<u>5/24/06</u> Date